

#13-25110
Supple Response
PATENT

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Date

February 18, 2000

Susan C. Clingerman

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : Michael T. Kelly, Raymond J. Andersen and Jeff Gerard

Application No. : 09/043,813

Filed : September 29, 1998

For : CYCLIC DECAPEPTIDE ANTIBIOTICS

Examiner : Anish Gupta

Art Unit : 1654

Docket No. : 850103.40301

Date : February 18, 2000

Assistant Commissioner for Patents
Washington, DC 20231

SUPPLEMENTAL RESPONSE

Claims 1-6 are presently pending in the Office Action. No claims have been canceled, added or amended.

In response to the Office Action dated June 9, 1999, Applicants filed a Response on December 9, 1999. That Response (incorrectly titled "Amendment") acknowledged that claims 1-4 stood provisionally rejected as being unpatentable over claim 54 of co-pending application number 08/751,300, now U.S. Patent 5,962,407, under the judicially-created doctrine of obviousness-type double patenting. That Response also indicated that Applicants did not

agree with the rejection. That Response further indicated that an executed Terminal Disclaimer would be submitted in order to obviate the rejection.

At the present time, Applicants submit the following argument to explain why the obviousness-type double patent rejection was improperly applied to pending claims 1-4. This argument is submitted in lieu of submitting a Terminal Disclaimer. Applicants request that the Examiner reconsider and withdraw the obviousness-type double patenting rejection in view of the following argument.

The Office Action supports the obviousness-type double patenting rejection by stating that the co-pending (now issued, see U.S. Patent 5,962,407) claim 54 is drawn to a pharmaceutical formulation whereas the claims 1-4 of the instant application are drawn to the compound. The Office Action concludes that such a variant is obvious because in producing the desired pharmaceutical formulations one would have to necessarily have the isolated compounds. The rejection is traversed for the following reasons.

The pending claims are directed to certain isolated compounds. However, the pharmaceutical formulations of the issued patent do not recite, or necessarily encompass, the isolated compounds of those pending claims. Thus, while the pending claims are directed to three specific peptides, the pharmaceutical formulations are directed to compositions that include various derivatives of the isolated compounds, *not the compounds themselves*. Accordingly, one would not necessarily need to have the isolated compounds in order to produce the pharmaceutical formulations. One could, for instance, prepare a derivative of a compound according to the synthetic methodology disclosed in, for example, Example A4 (col. 14, lines 26 to col. 16, line 39) of the issued patent, and then formulate that derivative into a pharmaceutical composition, while never generating or handling the "isolated compound" *per se*. Likewise, one could prepare salts of the derivatives, and then "underivatize" the salt in order to form a salt of the isolated compound that could be formulated into a pharmaceutical composition. Accordingly, it is definitely not the case that in order to produce the claimed pharmaceutical formulations, one would have to necessarily have the isolated compounds.

To summarize, the chemical species recited as being present in the pharmaceutical formulations (claim 54 of the issued patent) are not the same chemical species that are the subject

of the pending claims (1-4). Accordingly, one would not need the chemical species of pending claims 1-4 in order to prepare the pharmaceutical compositions of the issued patent.

Accordingly, reconsideration and withdrawal of the rejection are respectfully requested.

If any issue requires further discussion, the Examiner is encouraged to contact the undersigned to resolve the matter, at 206-622-4900.

Respectfully submitted,

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Enclosure:

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Art unit: 1654

FEB 22 2000

Filing date of application: September 29, 1998

Examiner assigned to application: Anish Gupta

GROUP 1600

Title of the invention: Cyclic Decapeptide Antibiotics

Attorney docket number: 850103.40301

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